



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

INAD 9006 H-0093

Dave Erdahl, Ph.D.
National INAD Coordinator
USFWS Fish Technology Center
4050 Bridger Canyon Road
Bozeman, Montana 59715

NOV 23 2001

Dear Dr. Erdahl:

We refer to your submission dated August 9, 2001, to your investigational new animal drug (INAD) file for the use of oxytetracycline at a dose of 3.7 g/100 lbs fish/day for 10 consecutive days for the control of mortality caused by coldwater disease in salmonids.

We have reviewed your submission and have the following comments.

Based on information in this submission, along with the effectiveness data previously accepted in our letter dated April 10, 2001, the Division of Therapeutic Drugs for Food Animals considers the effectiveness data requirements complete for the purpose of recommending approval of a New Animal Drug Application for the control of mortality due to coldwater disease caused by *Flavobacterium psychrophila* in freshwater-raised salmonids. A final decision on the approval of the application will be made when all the data for all technical sections are viewed as a whole and it is determined that the information contained in and referenced by the application supports approval.

Future correspondence regarding this letter should be identified by the date of this correspondence and our file number, INAD 9006 H-0093, and be addressed to the Document Control Unit, HFV-199. Please include only one request per submission, clearly stating the request in the first paragraph of the submission.

If you have any questions or comments regarding this correspondence, please telephone Dr. Joan Gotthardt, Leader, Aquaculture Drugs Team at 301-827-7571.

Sincerely yours,

Steven D. Vaughn, D.V.M.
Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine